APR 5 - 2007

K070390

EXHIBIT 2
510(k) Summary

VIRTUAL IMAGING

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January 18, 2007
Contact: Chris Duca, COO

1. **Identification of the Device:**
   Proprietary-Trade Name: FluoroPro RF Digital Imaging System
   Classification Name: System, x-ray, fluoroscopic, image-intensified
   Product Code Product Code JAA and LLZ.
   Common/Usual Name: Fluroscopic X-Ray System

2. **Equivalent legally marketed device:** Infimed Orion Digital Imaging System, K012490 (Now called PlatinumOne RF)..

3. **Indications for Use (intended use)** Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for obtaining fluoroscopic radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts. .

4. **Description of the Device:** The FluoroPro RF Digital Imaging System is a high resolution, digital imaging system designed for digital videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications where general fluoroscopy, interventional fluoroscopy or angiography or cardiac imaging procedures are performed. The FluoroPro RF Digital Imaging System allows the operator to view and enhance 1000 line fluoroscopy. High resolution digital spot images (1024 x 1024) may be acquired at single or rapid acquisition rates, up to 30 fps. Images may be viewed and enhanced enabling the operator to bring out diagnostic details difficult or impossible to see using conventional imaging techniques. Images can be stored locally for medium term storage. The FluoroPro RF Digital Imaging System enables the operator to hardcopy image with a laser printer or send images over a network for longer term storage. The major system components include: a fluoroscopic TV camera, monitors, and an image processor..

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart, "FluoroPro RF Digital Imaging System"**

Characteristic	Infimed Orion Digital Imaging System, K012490 (Now called PlatinumOne RF).	FluoroPro RF Digital Imaging System
Intended Use:	Acquisition, display, storage and transmission of fluoroscopic images	SAME
Power source	120 VAC 50/60 HZ 7 amps	120 VAC 50/60 HZ 2.5 amps
Image acquisition	Up to 15 FPS (spot), up to 30 fps (fluoro)	SAME
File compatibility	DICOM	SAME
CCD	Innovision CCD	Thales CCD
Digital Resolution	1024 x 1024 12 bit	SAME
Performance Standard	US FDA	SAME
Electrical safety	SAME	SAME

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Virtual Imaging that the FluoroPro RF Digital Imaging System is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Virtual Imaging, Inc.
% Mr. Daniel Kamm
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PO Box 7007
DEERFIELD IL 60015

AUG 21 2013

Re: K070390
Trade/Device Name: FluoroPro RF Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: February 2, 2007
Received: February 9, 2007

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of April 5, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070390

Device Name: FluoroPro RF Digital Imaging System

Indications For Use:

Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for obtaining fluoroscopic radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070390